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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,836	05/01/2001	Ian Baxter Campbell	PG3602USW	3589

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EXAMINER	
CHANG, CELIA C	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,836	CAMPBELL ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-10,17-23,26,28,29 and 35-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *7 and 35* is/are allowed.

6)☐ Claim(s) *1, 6, 8, 9, 18-23, 36-40* is/are rejected.

7)☐ Claim(s) *2-5,10,17,26 and 28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment and response filed by applicants dated Aug. 17, 2006 have been entered and considered carefully. Claims 11-16, 24-25, 27, 31-34 have been canceled. Claims 1-10, 17-23, 26, 28-29, 35 and newly added claims 36-40 are pending.

2. The rejection of claims 1-6, 8-9, 17-23 under 35 USC 2nd paragraph for the terms "pharmaceutically acceptable derivatives, "prophylaxis' "inflammatory disorder" "effective amount" "or other viral infections..." and "cognitive disorder" is dropped in view of the cancellation of such terms in the claims.

3. The rejection of claims 9, 18-23 under 35 USC 112 first paragraph for lacking description and enablement over the scope of "pharmaceutically derivatives" is maintained for reason of record and on the following grounds of new matter. The rejection is now applicable to the amended claims 1, 6, 8, 9, 18-23.

The term "derivatives" thereof has been amended to pharmaceutically acceptable salt, solvate, ester or amide or salt or solvate of such ester or amide for which description and enablement are lacking.

The only description for such compounds was found on pages 2-4 of the specification. The description of such derivatives were inclusive for intermediates for preparation p.4 2nd para), metabolite (p.2, 2nd para) or can provide the compound i.e. metabolizable to 9p.2 2nd para).

Chemically, a pharmaceutically acceptable acid addition salt is a variation which *upon in possession* of the compound of formula I can be formed with a conventional acid as described on page 3 3rd paragraph of the specification. However, solvates, ester or amide are independent entities which must acquired by itself to afford possession. Especially, there is absolutely no description where, how and with which solvents can a solvate, ester, amide or solvates of ester or amide be formed. None of the functional groups of R0, R1, R2 or R3 can be derivatized into such groups since such derivatization requires a free carboxylic acid moiety.

Further, such disclosure provides insufficient description as well as enablement for the claimed scope of "all solvates". The specification contains none of the compound , which is a

solvate. While a pharmaceutical addition salt can be prepared routinely upon in possession of an acid or basic compound, the solvate formation is the innate nature of a compound upon contacting certain solvent. Without any description of what solvent will form solvate with which compound and the complete silence of the existence of any solvate or hydrate, the specification offered mere language rather than possession or enablement of the solvates and the process of claim 12 failed to provided any enablement for a solvate or hydrate.

To the extend that the language is intended for any specific solvates, hydrates, ester or amide or solvates thereof, the claims are considered to contain NEW MATTER because any species that is not disclosed is new matter.

Removal of all new matter is required. In re Russmussen 210 USPQ 325.

4. Claims 29, 36-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed compounds are COX2 inhibitor for which applicants allege are useful in treating symptoms pain, fever or inflammation. While the compounds can be useful in treating the pain, fever or inflammation of arthritis, lower back pain dysmenorrhoea etc. of the claims other than the symptom (see Bandarage et al., Fenton et al. or Carter). Please note that no nexus of the compounds being useful in treating the etiology of the disease rather than the symptom.

It is recommended that claims 29, 36-40 be made dependent on claim 26.

5. Claim 7, 35 remain allowed.

Claims 2-5, 10, 17, 26, 28 are objected to as being dependent upon a rejected base claim, but would be allowable when the 112 issues of the base claims are resolved.

6. Applicants amendments necessitate the new grounds of rejection.

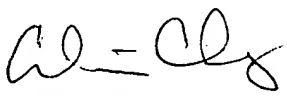
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



OACS/Chang
Oct. 23, 2006

Celia Chang
Primary Examiner
Art Unit 1625